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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,836	03/15/2006	Jialin Sun	09548.1019USWO	3476

52835 7590 06/06/2007

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EXAMINER	
GUSSOW, ANNE	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
06/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,836	SUN, JIALIN	
	Examiner	Art Unit	
	Anne M. Gussow	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2 and 11-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a fusion protein comprising a ligand that stimulates cancer cell growth or a peptide that directly interacts with cancer cell surface and a superantigen that may lead to an anti-cancer immune response. In view of this Kihara and Pastan (Cancer Research, 1994. Vol. 54, pages 5154-5159) reads on the claim. Kihara and Pastan teach a chimeric toxin comprised of a transforming growth factor α (TGFα) fused to *Pseudomonas* exotoxin (PE) which bind to the epidermal growth factor receptor and kill cells expressing the epidermal growth factor receptor. The TGFα is a peptide that directly interacts with a cancer cell surface and the PE is a superantigen. Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked at to form a single general concept under rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, and 11-16, drawn to a fusion protein.

Group II, claim(s) 17-18, drawn to a recombinant vector and host cell.

Group III, claim(s) 19; drawn to a method for producing a fusion protein.

Group IV, claim(s) 20, drawn to a method of preparing therapeutic agents for cancer or immune disease treatment.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teachings of Kihara and Pastan the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Groups I and III are related by product and method of using. Their shared technical feature is a fusion protein, but Forsberg, et al. teach a fusion protein. Group II requires nucleic acid which is not required for groups I, III or IV. Group IV requires a therapeutic agent which is not required for Groups I-III.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If Group I is elected, applicant is required to elect a species from the following group of ligands:

Species A: epidermal growth factor (EGF) family

Species B: vascular endothelial cell growth factor (VEGF) family

Species C: basic fibroblast growth factor bFGF and FGF family

Species D: transforming growth factor-α (TGF-α)

Species E: interleukin-4

Species F: interleukin-2

Species G: interleukin-6

Species H: interleukin-13

Species I: interleukin-3

Species J: granulocyte-macrophage colony-stimulating factor (GM-CSF)

Species K: heparin-binding EGF-like growth factor (HB-EGF)

Species L: insulin-like growth factor (IGF)

Species M: hepatocyte growth factor (HGF)

Species N: platelet-derived growth factor (PDGF)

Species O: nerve growth factor (NGF)

Species P: placental growth factor (PGF)

Species Q: stem cell factor (SCF)

Species R: interleukin-8

Species S: Ephrin family

Species T: Heregulin

Species U: erbB ligand

Species V: chemokine

Species W: angiopoietin (Ang)

Species X: thrombopoietin releasing hormone

Species Y: factor VII

Species Z: urokinase-type plasminogen activator (uPA)

Species AA: growth hormone releasing hormone

Species AB: gonadotropin-releasing hormone (GRH)

Species AC: α-melanocyte stimulating hormone (α-MSH)

Species AD: gastrin-releasing peptide (GRP)

Species AE: prolactin (PRL)

Species AF: prolactin releasing hormone (PRLH)

Species AG: growth hormone

Species AH: follicle stimulating hormone (FSH)

Species AI: placental lactogen (PL)

Species AJ: chorionic gonadotropin (CG)

Species AK: corticotrophin releasing hormone

Species AL: somatostatin

Species AM: asialoglycoprotein

Species AN: low density lipoprotein

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The species are receptors that bind a ligand of the fusion protein of claim 1.

The following claim(s) are generic: 1 and 12-20.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species are each receptors from different gene families, having different structures and different functions.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow, Ph.D.
May 11, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER